Outline for Case Management - Person with Latent TB Infection - LTBI

It is the responsibility of public health to ensure that persons with LTBI complete a treatment regimen that meets CDC protocols. The responsibility does not lie with the person or the physician, although their cooperation and collaboration are important and will make the responsibility easier for public health to meet. The initial assessment of the infected individual is extremely critical in order to select the necessary support and resources that will be needed from the public health department to ensure that the regimen is completed. **An individualized, person-centered plan for care and case management**, based upon the initial assessment, is essential to ensure that each LTBI regimen is completed and that the health department's rates of completion for LTBI regimens meet *or* exceed the quality threshold of 75% established by CDC. Directly Observed Therapy (DOT) may be necessary, especially for persons who are at risk of breaking down with active disease.[1.]

TREATMENT PROTOCOLS & STANDARDS OF PRACTICE

- **"Ensuring Treatment Adherence & Completion and Providing Directly Observed Therapy (DOT) for Persons with Suspect or Active TB Disease or Latent Tuberculosis Infection"** [1.] provides guidance on ensuring adherence to medication regimens.
- The medical diagnosis, treatment and monitoring of **LTBI for adults** is addressed in the new CDC Fact Sheet "**Treatment of Latent Tuberculosis Infection (LTBI)**" [2.], published in August of 2003.
- The diagnosis, treatment and monitoring of **children** and **adolescents with LTBI** is addressed in the new handbook "**Management of LTBI in Children and Adolescents: A Guide for the Primary Care Provider**". [3.]
- The Morbidity and Mortality Weekly Report **(MMWR) of June 9, 2000, Targeted Tuberculin Testing & Treatment of Latent Tuberculosis Infection** provides **comprehensive information** about the implementation of targeted tuberculin testing and the diagnosis and **treatment of LTBI**. [4.]
- The "**Wisconsin Antituberculosis Therapy Program Initial Request for Medication**", Form DPH 4000 (Rev. 08/03), provides comprehensive information about the strength of the recommended drug doses and regimens. Instructions on the information required for processing and approval of the request for medications are included. [5.]

OUTLINE OF DRUG REGIMENS [5.]

[Minimum doses/minimum time frames are for those who have a treatment interruption, such as for providing a "rest" for the hepatic system.]

"A" rating [6.] **Isoniazid [INH] Daily X 9 months** [Minimum 270 doses/12 months]
Adults = 5 mg/kg - up to a maximum of **300 mg** daily or
Children = 10-15 mg/kg - up to **300** mg daily, based on weight
*[INH dosing for children is **higher** than for adults; they generally tolerate INH better than adults.]*

"B" rating [6.] **INH Twice Weekly (DOT) X 9 months** [Minimum 76 doses/12months]
Adults = 15 mg/kg - up to a maximum of **900** mg/dose
Children = 20-30 mg/kg - up to **900** mg/dose

INH Daily X 6 months [Minimum 180 doses/9 months] Can be considered a complete regimen for an **HIV** *Negative adult* without fibrotic CXR lesions if 9 months of therapy is not possible.

INH Twice Weekly (DOT) X 6 months [Minimum 52 doses/9 months] Can be considered a complete regimen for an **HIV** *Negative adult* without fibrotic lesions if 9 months of therapy is not possible.

"B" rating [6.] (con't)

RIFAMPIN [RIF] **Daily X 4 months for Adults** [Minimum 120 doses/6 mo.]
RIFAMPIN [RIF] **Daily X 6 months for Children** [Minimum 180 doses/9 mo.]
Adults = 10 mg/kg - up to a maximum of 600 mg
Children = 10-20 mg/kg - up to a maximum of 600 mg
[*Can be used if the person is completely unable to take INH or they are a contact to a case of TB that is resistant to INH and susceptible to Rifampin. Cannot be given with many HIV medications.*]

"C" rating [6.] **INH** **Daily X 6 months for HIV+ Adults** [Minimum 180 doses/9 months] for adults
INH **Twice Weekly (DOT) X 6 months for HIV+ Adults** [Min. 52 doses/9 months]
These regimens are rated **"C"** for **HIV** Positive persons, those with **fibrotic CXR** lesions or **children**, (See above - *same* regimens have **"B"** rating for adults *or* children who are **HIV** *Negative* and do not have fibrotic lesions on CXR.)

"D" rating [6.] **Rifampin/Pyrazinamide [RIF-PZA]** *Generally* should not be used for LTBI treatment [7.]

In carefully selected patients for which the risk-benefit assessment indicates this regimen *is* needed, the preferred or alternative regimens are not likely to be completed and the oversight by a clinician with expertise in LTBI treatment can be provided, the regimen is not prohibited. A tuberculosis clinical expert should be consulted *before* RIF-PZA is implemented. Face-to-face clinical assessments along with laboratory monitoring every two weeks is minimal, including bilirubin as well as ALT and AST. [7.] If this regimen is prescribed and submitted to the Wisconsin TB Program, it will not be approved for payment until all of the required criteria for expert clinical over-sight of the patient are firmly established.

MINOR SIDE EFFECTS

Persons on LTBI treatment need comprehensive clinical assessments, encouragement, education, support and perhaps other prescription or over-the-counter medicines to help them tolerate *minor* side effects so that they can complete an LTBI treatment regimen. For instance, a rash may be assessed to need a medical evaluation. A physician may determine that itching or a slight skin rash may be managed with medications for symptom control and the person should continue the medication, or switch to an alternative LTBI treatment regimen. **Switching to an alternative LTBI treatment regimen when a person cannot tolerate INH is preferred over discontinuing therapy for a person with LTBI.** Collaboration between physicians and public health is essential to ensure the completion of the LTBI regimen.

Examples [not all-inclusive]:

INH - Tiredness, upset stomach [*extra rest, taking with food, taking in the evening may help*], Peripheral neuropathy - esp. tingling, hands, feet - [*taking pyridoxine-Vit B6 may help* [8.]]

Rifampin - Upset stomach [*take with food*], weakens oral contraceptives [*use additional birth control method*], orange-colored body fluids, etc.

SEVERE SIDE EFFECTS

Severe anorexia, vomiting or weakness that is not tolerable *may* be a symptom of the liver being affected, especially if the person also has right upper quadrant **abdominal pain**, fever, very **dark colored urine,** the whites of the **eyes** are **yellowed** or there are any other signs of hepatotoxicity.

LIVER ENZYME MONITORING for a HEALTHY PERSON

For most healthy persons the liver can tolerate INH but, the **clinical evaluation of the person's symptoms**, **both mild and severe is essential**. This helps the physician and public health staff to decide how the person is tolerating the medication. Assess for alcohol intake, other medications and any herbal preparation the person is taking that may be affected by INH or may contribute to hepatic stress (anti-seizure medications, for instance, or "statins" for cholesterol lowering.) Check up-to-date pharmacy information for potential drug interactions.

Routine monthly monitoring of LFTs is not generally indicated except for these circumstances:

- Abnormal baseline LFT
- Chronic liver disease
- Regular alcohol use
- HIV infection
- Pregnancy or immed. post partum
- Rifampin-Pyrazinamide regimen [7.]

Physicians *may* check baseline liver enzymes when persons are started on INH if they intend to use that information for comparison if symptoms develop. **Baseline clinical evaluation, including the nursing assessment, is essential**. Physician experts use the following parameters to evaluate for mild versus serious liver involvement:

- Persons **with** hepatitis symptoms - Hold medications if liver enzymes are **three** times normal
- Persons **without** symptoms - Hold medications if liver enzymes are **five** times normal [**Hold may be temporary**; some physicians **may restart** the INH if/when the person's enzymes and/or symptoms resolve or they may switch them to a different TB medication.] **Once a person is *confirmed* as infected with latent tuberculosis and starts treatment, completion is important, particularly if the person has any risk factors for progression to active disease. Incomplete treatment may contribute to the potential for later development of drug resistance. Patients *and* physicians need support, skillful monitoring and good communication links with public health to ensure the completion of treatment regimens, especially when side effects occur.**

PREGNANT WOMEN

INH is *not* prohibited for pregnant women and is not toxic to the unborn child, even during the first four months of gestation.[4.] However, in areas where TB is not common, most physicians will wait until after the post partum period to treat a pregnant woman diagnosed with LTBI under ordinary circumstances. However, if she has specific risk factors, such as being HIV Positive, or she has been recently infected, such as through close contact with an active disease case, treatment is *extremely important* to avoid progression to active disease in the woman and to prevent TB from spreading to the infant during gestation.

ALCOHOL INTAKE

Persons should not consume alcohol when taking tuberculosis medications because alcohol causes additional strain on the liver. Treating severe alcohol addiction may need to precede treatment for LTBI. The risks versus the benefits of treatment must be evaluated; alcoholics may need DOT in order for an LTBI regimen to be completed.

CONTINUITY OF CARE

Many persons on LTBI treatment are quite mobile and may be likely to relocate within the treatment period. The guideline "Accessing Services and Resources for Persons with Suspect or Active Tuberculosis Disease or LTBI", describes using a summary letter for referral. The **Interjurisdictional Tuberculosis Notification Form (DPH 42010)** now streamlines the paperwork process and makes writing a summary letter unnecessary unless additional information must be explained. The TB Program will help locate the out-of-state health department for your referral when provided with the new address. Telephone contact, PHN to PHN should be done whenever possible.

REFERENCES & ADDITIONAL INFORMATION

1. **Ensuring Treatment Adherence & Completion and Providing Directly Observed Therapy** for Persons with Suspect or Active TB Disease or Latent Tuberculosis Infection, is available on the Wisconsin TB Program Web site at www.dhfs.wisconsin.gov/dph_bcd/tb

2. **Treatment of Latent Tuberculosis Infection (LTBI), TB Elimination Fact Sheet**, Document # 250110, Centers for Disease Control and Prevention (CDC), August 2003, available on the TB Elimination Web site at http://www.cdc.gov/tb

3. **Management of LTBI in Children and Adolescents: A Guide for the Primary Care Provider**, New Jersey Medical School National Tuberculosis Center, 2003, available on the New Jersey TB Center's Web site at http://www.umdnj.edu/ntbcweb

4. **Targeted Tuberculin Testing & Treatment of Latent Tuberculosis Infection**, Morbidity and Mortality Weekly Report **(MMWR) of June 9, 2000**

5. **Wisconsin Antituberculosis Therapy Program Initial Request for Medication**, Form DPH 4000 (Rev. 08/03) is available on the Wisconsin TB Program Web site at www.dhfs.wisconsin.gov/dph_bcd/tb

6. **CDC Rating Scale**: A = preferred; B = acceptable alternative; C = offer when both A *and* B cannot be given; D = should not *generally* be given; E = should never be given

7. **CDC Update: Adverse Event Data and Revised ATS/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection**, MMWR 2003; 52 (No. 31)

8. **Frequently Asked Questions about Pyridoxine (Vitamin B-6)** is available on the Wisconsin TB Program Web site at www.dhfs.wisconsin.gov/dph_bcd/tb